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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,345	12/01/2003	Johanna G. H. Ruseler-van Embden	2183-6192US	5255
24247	7590	05/30/2007		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER AFREMOVA, VERA	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 05/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/727,345	RUSELER-VAN EMBDEN ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-27 is/are pending in the application.
- 4a) Of the above claim(s) 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-19 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/19/2007 has been entered.

Claims 1, 2, 6-19 as amended and new claim 27 (3/19/2007) are under examination.

Claims 20-26 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s).

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EPO on 5/20/1998. It is noted, however, that applicant has not filed a certified copy of the EPO application as required by 35 U.S.C. 119(b).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. New claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,906,457 (Ryan) in the light of evidence by Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claim 27 is directed to a skin care or topical pharmaceutical composition comprising 1) a proteolytic activity inhibitor derived from potato and 2) a cosmetically or pharmaceutically acceptable vehicle.

US 4,906,457 (Ryan) discloses a skin care or topical pharmaceutical composition comprising an inhibitor of proteolytic activity that is derived from potato and a cosmetically or pharmaceutically acceptable vehicle (col. 3, lines 58-65). In particular, the composition comprises potato derived protease inhibitor in amounts about 0.01%, glycerol and water (example 1). The potato inhibitor I is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. The cited patent teaches the use of protease inhibitor in amounts approximately 10 mg/ml or higher in the topical composition (col. 2, line 24) or the use of protease inhibitor in desired proportions (col. 3, line 33). The composition is in a form of lotion, gel or aqueous solution, etc (example 1 or col. 2, lines 35-40) and contains additional generic materials suitable as generic emollients, thickeners, and preservatives within generic meaning of "emollients", "thickeners" and "preservatives". The composition with protease inhibitor is applied to the skin, it is incorporated into various articles of manufacture including brush, wipe, etc. (col. 3, line 55) and the aqueous composition with protease inhibitor is provided in containers or dispenser. The composition of example 2 contains more than 50% of water within the broadest meaning of "Lanette cream" (claim 12).

Thus, the composition of US 4,906,457 (Ryan) is identical to the claimed composition and, therefore, US 4,906,457 (Ryan) anticipates the claimed invention.

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2. New claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by US 3,950,509 (Geks et al) in the light of evidence by Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claim(s) as above.

US 3,950,509 (Geks et al) discloses a skin care or topical composition comprising a cosmetically or pharmaceutically acceptable vehicle and a proteolytic activity inhibitor derived from potato (examples 3-4 at col. 3, line 32 and line 40; col. 4, line 1 and line 19) including kallikren-trypsin inhibitor derived from potatoes (col. 2, line 5 and example 1). The potato inhibitor is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. The potato-derived inhibitor is present in amounts from 1.5 wt. % (col. 2, line 54; col. 3, line 3) to about 3 wt. The composition is in a form of lotion, gel or aqueous solution, etc (col. 2, lines 25-27; examples 1 and 2) and contains additional generic materials suitable as generic emollients, thickeners, preservatives (see examples 1-4) within generic meaning of "emollients", "thickeners" and "preservatives". The composition with protease inhibitor is applied to the skin, it is incorporated into various articles of manufacture including cloth (col. 3 , line 5) and the aqueous composition with protease inhibitor is provided in containers or dispenser. The composition of example 2 contains more than 50% of water within the broadest meaning of "Lanette cream" (claim 12).

Thus, the composition of US 3,950,509 (Geks et al) is identical to the claimed composition and, therefore, US 3,950,509 (Geks et al) anticipates the claimed invention.

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3. New claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Rodis et al ("Naturally occurring protein crystals in the potato". Plant Physiol. 1984, 74:907-911) in the light of evidence by Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462).

Claim(s) as above.

The cited reference by Rodis et al discloses a composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle such as sodium acetate buffer, for example: see page 909, col. 2, last par., lines 1-2. The potato inhibitor is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract. The particular composition has pH of about 4-5. The cited reference also teaches that potato-derived proteins such as inhibitors of proteolytic activity are readily dissolved at pH 4-5. The aqueous solution(s) can be absorbed into wipe, sheet, etc and they contain 50% water and more within the broadest meaning of the claims 2, 5, 6, 8, 12 and 13.

Thus, the composition of the cited reference by Rodis et al is identical to the claimed composition and, therefore, the cited reference by Rodis et al anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-19 as amended and new claim 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) taken with Rodis et al ("Naturally occurring protein crystals in the potato". Plant Physiol. 1984, 74:907-911), Pearce et al. (IDS reference; Archives of Biochemistry and Biophysics. 1982, Vol. 213, No. 2, pages 456-462) and US 4,685,909 (Berg et al.).

Claims are directed to a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato in amounts 1-20% and a cosmetically or pharmaceutically acceptable vehicle wherein the composition has pH of about of 4.8-5.5. Some claims are further drawn to the vehicle being in form of lotion, gel or aqueous solution, etc. Some claims are further drawn to the use of additional materials including adjuvant and some generic emollients, thickeners, preservatives and water. Some claims are further drawn to the composition being incorporated into various articles including wipe, cloth or dispenser.

US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) are relied upon as explained above for the disclosure of a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. The potato inhibitor is a protease inhibitor, thus, it is inherently characterized by activity against proteases including trypsin and elastase as evidenced by the IDS reference by Pearce et al., for example: see abstract.

US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) teaches incorporation of potato protease inhibitor in amounts within the presently ranges. The cited US 4,906,457 teaches incorporation of potato protease inhibitor in amounts 1% or 10 mg/ml and higher in the topical composition (col. 2, line 24) or the use of protease inhibitor in desired proportions (col. 3, line

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33). The cited US 3,950,509 (Geks et al) teaches incorporation of potato-derived inhibitor in amounts from 1.5 wt. % (col. 2, line 54; col. 3, line 3) to about 3 wt. The cited references also teach and suggest that the amounts of active ingredients and genetic carriers can be adjusted as desired to provide for compositions in various forms.

The cited patents are silent about pH of the compositions with potato protease inhibitors. However, the reference by Rodis et al teaches that potato protease inhibitors remain active at least within the pH range from 4 to 8 (Fig. 6).

Furthermore, US 4,685,909 (Berg et al.) is relied upon for the teaching of incorporation of acidic pH control agents suitable for maintaining skin pH within ranges 3-5.5 in the skin care or topical compositions intended for alleviation of inflammation caused by proteolytic activity of feces, for example: see entire document including col. 2, lines 66-68 and col. 1, lines 50-68).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use acidic pH in topical compositions of US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) with a reasonable expectation of success in maintaining activity of potato-derived protease inhibitors, in maintaining skin natural acidity and in inhibiting irritation-producing enzymatic activity present from human and animal excrements. One of skill in the art would have been motivated to use acidic pH for making compositions with potato-derived protease inhibitors for the expected benefits in inhibiting irritation-producing enzymatic activity present from human and animal feces and urine.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.



The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

***Response to Arguments***

Applicant's arguments with respect to the amended and new claims have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that new claim 27 recites "alleviation of inflammation caused by proteolytic activity of feces", it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With regard to the cited patents US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) applicants appear to argue that the prior art does not teach or suggest incorporation of proteolytic activity inhibitor derived from potato in amounts 1-20%. Upon review of the references it is not found true. The cited US 4,906,457 teaches incorporation of potato protease inhibitor in amounts 1% or 10 mg/ml and higher in the topical composition (col. 2, line 24) or the use of protease inhibitor in desired proportions (col. 3, line 33). The cited US 3,950,509 (Geks et al) teaches incorporation of potato-derived inhibitor in amounts from 1.5 wt. % (col. 2, line 54; col. 3, line 3) to about 3 wt. The cited references also teach and suggest that the amounts of active ingredients and genetic carriers can be adjusted as desired to provide for compositions in various forms. At least some of the instant claims are directed to a product such as a diaper or a wipe

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wherein the amounts of potato-derived inhibitor(s) would obviously be adjusted to incorporate less than 20% by weight of the total product or an article of manufacture.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

May 18, 2007



VERA AFREMOVA

PRIMARY EXAMINER